Remarks

Claims 30-35 were pending. Claims 30, 32, 33 and 35 are canceled herein without prejudice to renewal or refilling of the original scope. Claims 31 and 34 have been amended. No new matter is added. Applicants respectfully request reconsideration of the rejections.

Claims 33 - 35 have rejected under 35 U.S.C. §112 as lacking written description. Rejections made to canceled claims 33 and 35 are made moot and will not be further considered.

The Office Action states that the specification does not demonstrate the claimed invention by describing a compound identified using the present methods. Applicants respectfully submit that the demonstration of an identified compound is not necessary in order to convey to the skilled person that the inventors had possession of the invention. The provision of screening methods to identify compounds that either inhibit or enhance an interaction is well known in the art and a skilled person can readily design and perform suitable screening methods for any interaction which is known in the art. Screening methods follow directly from the recognition and characterization of the interaction, which is fully described in the specification. The methods described in the specification require no more than routine experimentation (i.e. the addition of a test compound) in order to be used for screening. The skilled person would understand from the specification that the skilled person was in possession of the claimed screening methods.

Furthermore, the measurement of ATM associated p53 kinase activity, which is described for example on page 78 lines 18 to 26 of the specification, provides a screening method. DNA is added to the reaction medium in varying amounts (0 to 30 fmol) and is shown to markedly stimulate ATM and ATR associated p53 kinase activity (see page 71 lines 26-27). Thus, DNA fulfils the requirements of a test compound and the identification of this molecule as having a positive (agonistic) effect on phosphorylation demonstrates an example of the claimed screening methods.

The Examiner also observes that the claimed methods do not include a step to separate or detect the compound sought. The claims relate to methods for identifying a compound with modulating activity. If a test compound is found to alter the phosphorylation of p53, then it is identified as a modulator. There is no need to separate or detect the test compound at any stage in order to perform the method. Thus, the addition of further steps to the claims is unnecessary.

The Examiner also alleges that the use of the term 'modulate' raises issues of written description. However, this is not the case. As noted by the Examiner, the term 'modulate' encompasses positive and negative effects. However, this is a small and defined genus of possible effects (i.e. two possible effects), which are readily determined by the skilled artisan using precisely the same screening methods. Given the recognition and characterization of the ATM/ATR mediated p53 phosphorylation by the inventors, the skilled artisan is readily able to screen for both positive and

negative regulators, using exactly the same methodology. For example, the exemplified methods to identify DNA as having a positive effect could equally be used to identify other compounds that produce a negative effect.

Furthermore, the results of the claimed screening methods are predictable and will always yield one of three possible outcomes for any compound tested: no effect, positive effect or negative effect.

The disclosure of the specification would be sufficient to convey to the skilled person that the inventors had possession of the screening methods for both positive and negative acting compounds and no issues of written description arise from the use of the term 'modulate'.

The present claims are directed to ATM or ATR or fragments thereof which phosphorylate p53. The genus defined by the claims includes fragments that have p53 kinase activity, and excludes fragments which lack p53 kinase activity.

p53 kinase activity is a distinguishing attribute which characterizes all the members of the genus defined by the claims and limits the structural variation permitted between members of the genus. A skilled person is readily able to detect and measure p53 kinase activity using the methods set out in the specification. The ATM domain responsible for the kinase activity is shown in Figure 6a.

The applicant was therefore in possession of the claimed genus when the invention was made and the invention is adequately described in the specification. The present claims therefore meet the requirements of 35 USC §112 first paragraph (Written description).

Claims 30-35 have been rejected under 35 U.S.C. §112 second paragraph. Claim 30 has been cancelled rendering moot rejections thereof.

Claim 31 has been amended to spell out the meaning of the acronyms ATM and ATR and to provide a nexus between the preamble and the end point.

The Examiner alleges that the use of the term 'modulate' renders the claims indefinite. This is not the case. The term 'modulate' has a clear and definite meaning in varying or altering an activity and encompasses both positive and negative effects. The mere fact that the term is broad enough to encompass both these possibilities does not make it indefinite. Breadth is not the same as indefiniteness, and this is clearly stated at MPEP 2173.04:

> *Breadth of a claim is not to be equated with indefiniteness.*
> In re Miller, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)

The correct test for indefiniteness is set out in MPEP2173.02:

> The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification."

Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

A person skilled in the art would, like the Examiner, understand that the term 'modulate' in the present claims relates to both positive and negative effects and the claimed screening methods are suitable for the identification of compounds which have both positive and negative effects on ATM mediated p53 phosphorylation.

The present claims therefore meet the requirements of 35 U.S.C. §112, first and second paragraph. In view of the above amendments and remarks, withdrawal of the rejection is requested.

Claims 30, 32, 33 and 35 have been rejected under 35 USC §103 as unpatentable over Hoekstra et al in view of Jongmans et al.

Claims 30, 32, 33 and 35 have now been cancelled, rendering moot rejections thereof.

The present claims therefore meet the requirements of 35 U.S.C. §103 (a). Withdrawal of the rejection is requested.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MEWE-010.

Date: Aug. 4, 2004

Respectfully submitted,
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